

### Election of Species

Applicants hereby elect, with traverse, the species 4-hydroxy-2,2,6,6-tetramethylpiperidine-1-oxyl (Tempol). Tempol is a compound of formula I in which  $R_1$  is O·, each of  $R_2$ ,  $R_3$ ,  $R_4$  and  $R_5$  is methyl (a  $C_{1-20}$  alkyl group),  $n=1$ , one of  $R_6$  and  $R_7$  is hydrogen and the other is hydroxyl, and each of  $R_8$ - $R_{11}$  is hydrogen. Claims 1-3 and 22-27 read on the elected species.

### Discussion of Requirement for Election of Species

The election of species requirement is improper. Although the Office notes that the claims recite numerous variables with allegedly widely divergent meanings, the Office admits that it can not provide a precise listing of inventive groups. The Office merely renders broad assertions that the claims "are generic to a plurality of disclosed species comprising formula I or II" and that the species lack unity of invention and "the same or corresponding special technical features that defines [sic] a contribution over the prior art" (see Office Action, page 2, paragraph 1). Such assertions are insufficient to support a requirement for election of species. Rather, according to M.P.E.P. § 1893.03(d), "[w]hen making a lack of unity invention requirement, the examiner must (1) list the different groups of claims and (2) explain why each group lacks unity with each other group (i.e., why there is no single general inventive concept) specifically describing the unique special technical feature in each group." Thus, it is evident that the examiner has failed to meet the requirements for a proper lack of unity rejection and the requirement for election of species should be withdrawn.

In addition to the above, Applicants point out that the claims are not directed to the compounds of formulae I and II, themselves. Rather, the claims are directed to a method for the prophylactic or therapeutic treatment of cancer in an animal. The method comprises administering to an animal at risk for developing cancer or having a cancer a nitroxide or a prodrug thereof in an amount sufficient to prevent or treat cancer. In addition, any suitable nitroxide or prodrug thereof can be used in the context of the instantly claimed method. Thus, the claims also are not directed solely to the use of the compounds of formulae I and II.

In view of the above, there is a single general inventive concept -- the use of a nitroxide (or prodrug thereof) in the treatment of cancer. The special technical feature of the compounds used in the treatment of cancer in accordance with the present invention is that the compounds are nitroxides (and prodrugs thereof). The special technical feature common to the compounds of formulae I and II is that the compounds are nitroxides (and prodrugs thereof) having nitrogen-substituted rings and substituents  $R_1$ - $R_7$ ,  $R_{10}$  and  $R_{11}$  in common. Accordingly, Applicants request withdrawal of the requirement for election of species. In this regard, while the Office alleges that it would be burdensome to search all of the species, Applicants point out that the Office has failed to provide evidence of an undue burden.

#### Conclusion

The application is considered to be in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



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M/Clients/NIH/Amd/175931rrr

CERTIFICATE OF MAILING

I hereby certify that this RESPONSE TO RESTRICTION REQUIREMENT (along with any documents referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

Date: 12/15/2000

Elizabeth M. Campbell